K003882

FEB 21 2001

510(K) SUMMARY

SUBMITTER IDENTIFICATION

Applicant's Name and Street Address: IS^2 Research Inc.
20 Gurdwara Road, Units 3 - 6,
Nepean, Ontario, Canada
K2E 8B3

Contact Person: Victor Woodburn, Manager Quality and Regulatory

Telephone and Fax Numbers of Contact Person: T - (613) 228-8755, F - (613) 228-8228

Address of Manufacturing Site: same as Applicant's address above

Date of Submission: November, 2000

DEVICE NAME

Device Name (common): Gamma Camera
Proprietary Name: NuCamma Bi90
Classification Name: Emission Computed Tomography System

INTRODUCTION

This 510(k) Premarket Notification has been prepared to demonstrate that the NuCamma Bi90 , manufactured by IS^2 Research Inc., is substantially equivalent to the Elscint SPX gamma camera which has previously underwent the 510(k) premarket notification process. The NuCamma Bi90 nuclear imaging system has two rectangular field of view detector heads.

INTENDED USE

The intended use of NuCamma Bi90 is to detect the location and distribution of gamma ray emitting radionuclides in the body and store the data for analysis. This device includes accessories such as signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the two devices is identical .The system does not include data analysis capability. The data is stored and available for transmission to, or retrieval by, existing commercially available data analysis software and accompanying computer equipment.
The NuCamma Bi90 has been deemed safe and effective and is certified to the same electrical safety standards as the predicate device by a third party organization prior to use on patients. A matrix was constructed comparing the features and intended use of the NuCamma Bi90 with the predicate device. We conclude that the NuCamma Bi90 is substantially equivalent to the predicate device and that no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Mr. Victor Woodburn
Manager, Quality and Regulatory
IS2 Research Inc.
20 Gurdwara Road
#3-6, Nepean ON K2E 8B3
CANADA

Re: K003882
NuCamma Bi90 System (SPECT)
Dated: December 8, 2000
Received: December 15, 2000
Regulatory Class: II
21 CFR §892.1200/Procode: 90 KPS

Dear Mr. Wooburn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003882

Device Name: GAMMA CAMERA (NuCAMMA Bi90)

Nuclear Medicine Device

Indication For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s):

	YES	NO	Energy Range (keV)
A. Planar Imaging	✓		50-400
B. Whole Body Imaging	✓		50-400
C. Tomographic imaging (SPECT) for non Positron emitter	✓		50-400
D. Positron imaging by coincidence		✓	
E. Positron imaging without coincidence		✓	
F. Other indication(s) in the device label, but not included in above list			

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David C. Segmm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003882